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No. 94-1527

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

BARR LABORATORIES, INC.,
Petitioner,

v.

BURROUGHS WELLCOME CO.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITIONER'S SUPPLEMENTAL MEMORANDUM IN REPLY TO BRIEF OF THE UNITED STATES

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RULE 29.6 STATEMENT

Barr Laboratories, Inc. has no parent company. Barr has two subsidiaries, BRL Incorporated and 265 Livingston Street Corp.

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Petitioner Barr Laboratories, Inc. (Barr) files this supplemental memorandum in reply to the brief of the United States as amicus curiae. S. Ct. R. 15.8.

STATEMENT

This case deals with conception in the experimental field of biological science and with joint invention, which has been called "one of the muddiest concepts in the muddy metaphysics of patent law." *Mueller Brass Co. v. Reading Indus.*, 352 F. Supp. 1357, 1372 (E.D. Pa. 1972), *aff'd*, 487 F.2d 1395 (3d Cir. 1973). What constitutes conception of a joint invention in that context is in need of clarification by this Court.

Barr does not contend, as the Solicitor General claims, that in every instance "an inventor must have a reason-

able expectation that an invention will work in order to conceive the invention for purposes of federal patent law." *See* Brief for the United States as Amicus Curiae (U.S. Brief) I. Such a belief is needed only for invention *in an uncertain and experimental field such as biological science.* Petition (No. 94-1527) (Barr Pet.) i. Where an invention is

> a method of treating the human body . . . , conception thereof is a far different thing than merely thinking of the use of the compound. *There must be some concomitant reasonable understanding or appreciation of the fact that the compound* [*will*] *work and in what way.*

Biel v. Chessin, 347 F.2d 898, 902-03 (C.C.P.A. 1965) (Rich, J.) (emphasis added).

DISCUSSION

The court of appeals has interpreted the "conception" component of invention far too loosely, and at variance with the Constitution and the patent code. Further, Federal Circuit precedent is inconsistent and the Executive Branch has taken inconsistent positions as well (indeed, even within this litigation). At bottom, though, this case merits review not so much for these inconsistencies as because the court of appeals has decided wrongly an important issue of federal law. S. Ct. R. 10(c).

The Solicitor General does not dispute that under the fact pattern set out in Barr's reply brief, Ms. *A* is the sole inventor and Dr. *B* has no rights in the invention.[1] *See* Petitioner's Reply Memorandum (No. 94-1527) (Barr

[1] Indeed, although Barr's hypothetical posits only one compound, Barr Reply Mem. 1, the decision of the court of appeals apparently would be the same if a multitude of compounds were involved. *See MacMillan v. Moffett*, 432 F.2d 1237 (C.C.P.A. 1970) (69 compounds). In this case BW selected 113 compounds, submitted 19 (including AZT) to Duke University and the FDA for the unsuccessful testing by those entities, and submitted six to Dr. Broder for testing at the NIH.

Reply Mem.) 1-2. Instead he contends that (assuming one includes the decision Barr is asking this Court to review) the Federal Circuit's conception jurisprudence is internally consistent. U.S. Brief 9-15. Although Barr disagrees, *see* Barr Pet. 16-18; Barr Reply Mem. 4-6, the consistency point is secondary. The primary point is that the Federal Circuit has set the threshold for conception in the area of biological science far below what is envisaged by our patent law.

There are decisions of the Federal Circuit and its predecessors supporting the "reasonable expectation" test, *e.g.*, *Biel*, 347 F.2d 898; *Smith v. Bosquet*, 111 F.2d 157 (C.C.P.A. 1940); *Amax Fly Ash Corp. v. United States*, 514 F.2d 1041, 1048 (Ct. Cl. 1975), and its close relative, simultaneous conception and reduction to practice, *Smith*, 111 F.2d 157; *Alpert v. Slatin*, 305 F.2d 891 (C.C.P.A. 1962). Further, the Solicitor General concedes that "precedents such as *Applegate* [*v. Scherer*, 332 F.2d 571 (C.C.P.A. 1964)] and *MacMillan* [*v. Moffett*, 432 F.2d 1237 (C.C.P.A. 1970)]," which are relied upon by BW, Brief in Opposition (No. 94-1527) 12-13, "hold only that an inventor does not need to *know* that his invention will work," U.S. Brief 12 n. 1 (emphasis in original), and hence do not rule out the reasonable expectation test. He excuses this flaw by claiming that *MacMillan* impliedly is inconsistent with such a test. *Id.* But Barr does not rely on *MacMillan*,[2] which—like the case at bar—invites abuse. Barr Pet. 18.[3] Under

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[2] *Applegate* involved only a single compound, which Scherer had more than a reasonable expectation would work for the intended use. *Applegate*, 332 F.2d at 572.

[3] *MacMillan* is inapposite for another reason: MacMillan was not a coinventor because he " 'was merely conducting standard tests.' " *MacMillan*, 432 F.2d at 1240 (quoting Board of Patent Interferences). Like the Federal Circuit, which conceded that the NIH scientists "exercised considerable skill" and that their testing "necessarily involved interpretation of results for which [the NIH researchers] were *uniquely qualified*," Barr Pet. App. 14a-15a

MacMillan and the decision here, a would-be inventor with any number of chemical compounds on hand—be it sixty-nine, *see MacMillan*, 432 F.2d at 1238, or thirty thousand, *see* Barr Pet. 17; Barr Pet. App. 38a—can select a disease, name each compound in a boilerplate patent application form like BW's, and thereby satisfy the Federal Circuit's conception requirement without even lodging the "applications" anywhere beyond his or her own file room.

When conception supposedly occurred, BW did not believe that the activity of AZT (or of the more than 100 other compounds tested by BW) against murine retroviruses was predictive of activity against the human immunodeficiency virus (HIV). *See* Barr Pet. App. 31a. Indeed, BW concedes that AZT's "potential medical value was not realized until [BW] had the compound tested *in vitro* against the AIDS virus . . . and found it to have especially potent activity against the virus." Fed. Cir. Appendix A5930-31 (1987 affidavit of BW patent agent). That is why BW's scientists could not have had any reasonable expectation that AZT would work against HIV until after receiving the *in vitro* test results from the NIH.

Like the Federal Circuit, the United States has taken inconsistent positions on the conception/joint inventorship issue. In describing the license agreement between the NIH and Barr, U.S. Brief 4, the Solicitor General omits a crucial representation by the government: "[NIH] investigators *conceived and reduced to practice*" the invention. Fed. Cir. Appendix A5386 (Patent License agreement between NIH and Barr, App. D, § 1.01 (July 1991) (emphasis added) (NIH-Barr Agreement)). Barr has been advised that the Department of Justice reviewed and approved the NIH-Barr Agreement before it was executed. Further, NIH previously had told BW that NIH's scientists "should have been named as coinventors" and

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(emphasis added), the Solicitor General concedes that the work of the NIH scientists was anything but "standard," U.S. Brief 8-9.

had requested BW's "cooperation in correcting inventorship." Trial Exh. 2193 (Letter from William Raub, Act'g Dir., NIH, to Philip Tracy, Pres. BW (Dec. 28, 1990)), at 1 (Appendix to this memorandum at 1a). Dr. Raub added that NIH's

> assertion of inventorship rights . . . is consistent with Federal patent law and is the culmination of a thorough review . . . . In reaching our conclusion on inventorship, we carefully reviewed our records of the underlying research collaboration, the various public statements and Congressional testimony of officials of [BW], and the prosecution histories of the relevant U.S. patents. We also conducted a detailed analysis of this case, including consultation with outside patent counsel.

Id. at 2 (App. 2a-3a). Thus the Executive Branch, like the Federal Circuit, is of different minds about what constitutes conception. This is further evidence of the need for review.

The Solicitor General correctly states that the doctrine of simultaneous conception and reduction to practice applies where an inventor is proceeding by trial and error. U.S. Brief 13; *see Alpert*, 305 F.2d at 894. This is because the inventor does not yet have the definite and permanent idea that the law requires. U.S. Brief at 13. He then argues that no such issue is presented here because the draft BW application supplies the requisite evidence of a such an idea. *Id.* 13-14. That contention is incorrect: First, before BW sent AZT to the NIH for testing, researchers at Duke University and the FDA had tested AZT for BW *without positive results*. *See* Barr Pet. 5-6. These experimental failures must have undermined the "fixed" character of any idea on BW's part that AZT would work against AIDS. At a minimum, Barr should have been permitted to adduce evidence on this issue at trial. Second, the all-encompassing, boilerplate character of the draft U.K. application deprives it of any claim to be "definite."

Unable to explain away the "reasonable understanding or appreciation" language of *Biel*, the Solicitor General argues (as did the Federal Circuit) that the statement hasn't been treated as controlling in subsequent cases. U.S. Brief 14. But in 1975 the Court of Claims (a predecessor of the Federal Circuit), citing *Biel*, ruled against a defendant's claim of prior conception of the plaintiff's patented method for controlling abandoned mine fires:

> [I]t is insufficient, on the issue of prior conception, merely to show prior knowledge of the broad idea of hooking up a pneumatic tanker to a borehole extending into a mine cavity. Rather, it must be shown that, in addition to this broad idea, there was a realization, *in finite terms*, of the means or process steps by which the desired result of extinguishing a fire would be achieved.

Amax, 514 F. 2d at 1048 (emphasis added). No other reported citations of *Biel* appear to be with respect to its reasonable expectation aspect. This hardly is evidence that *Biel* was unsound when written or no longer is good law. At most it may suggest that the issue has not come before the Federal Circuit squarely until now.

The Solicitor General chides Barr for citing dictum, U.S. Brief 14, but employs that practice himself in the fruitless quest for a holding of this Court supporting his portion. *The Telephone Cases*, 126 U.S. 1 (1888) (4-3 decision), cited at page 10 of his brief, involved not conception but the other component of invention—reduction to practice. *See id.* at 535-38 ("[I]t is conceded that [Bell] was acting on the right principle and had adopted the true theory").

The Solicitor General disregards the overbroad, boilerplate character of BW's draft U.K. patent application. *See* Barr Reply Mem. 2-4. This goes to whether that application provided the requisite corroboration of BW's claim of conception, which it did not. *See* Barr Pet. App. 13a. In *Meitzner v. Corte*, 410 F.2d 433 (C.C.P.A. 1969),

the inability to appreciate which parameters of the unnamed diluent were particularly significant or how the parameters should be varied to render a given diluent useful was held a failure of conception, *id.* at 438. Similarly, BW's inability to appreciate which route of administration, dosage form, dosage frequency, or dosage size might be effective rendered BW's supposed conception incomplete.

The Solicitor General, U.S. Brief 7, 11, 13, repeats the court of appeals' claim, Barr Pet. App. 13a, that Barr conceded BW's draft U.K. application was an enabling disclosure. Barr did not and does not so concede. This point is important because conception has two elements: formulating a definite and permanent idea *and* corroborating that formulation (e.g., by making "an 'enabling' disclosure—that is, 'a disclosure which would enable a person of ordinary skill in the art' to practice the invention," U.S. Brief 7). Without such corroboration there is no conception, yet the court of appeals permitted a preformatted "disclosure" covering the universe of pharmaceutical delivery options to serve that function. The district court said that Dr. Alexandra Levine, a Barr expert, conceded this point in her deposition. Barr Pet. App. 29a & n. 3. Dr. Levine, who was not a retrovirologist but a clinician treating AIDS patients, *see* Levine Dep. 27, 29, 41-42 (Appendix to this memorandum at 5a-6a), was asked whether she physically *could* have administered AZT to a patient using the universal list of dosage forms, the infinite range of dosage frequencies, and the broad range of dosage amounts set out in the BW U.K. draft application, *id* 55-58 (App. 6a-8a). Dr. Levine pointed out that although she *could* have administered the compound, she *would not* have done so given the high dosages encompassed with the application, *id.* 55-56 (App. 6a-7a), and the absence of any expectation that the drug would work, *id.* 69-71 (App. 8a-10a). When pressed, she stated that she physically *could* administer the drug. *Id.* 57-58 (App. 7a-8a). This is not a concession of enablement or

corroboration. Physicians are the individuals "skilled in the art" where drugs are concerned and, as Dr. Levine testified, no ethical physician would have administered AZT to a human being to treat HIV or AIDS based upon BW's draft U.K. application. *Id.* 69-71 (App. 8a-10a).

It is not enabling to say that if an undetermined amount of one of any number of compounds, prepared using one of the dozen or so recognized dosage forms, is inserted through one of the various bodily orifices (or injected through the skin) an undetermined number of times, the drug will treat HIV. More specificity is necessary, else anyone with a warehouse full of chemicals could designate them all as potential cures for cancer and then "corroborate" the idea or make an "enabling disclosure" by filling in the name and a diagram of each compound in the space provided in BW's boilerplate form. "[W]hen everything is classified, then nothing is classified, and the system becomes one to be disregarded . . . and . . . manipulated." *New York Times Co. v. United States*, 403 U.S. 713, 729 (1971) (Stewart, J., concurring). Similarly, when everything is enabled, nothing is enabled and—as the case at bar demonstrates—comparable mischief is engendered.

The Solicitor General next argues that a low conception threshold will cause no harm because a patent application must clear such other hurdles as utility, novelty, and nonobviousness. *See* U.S. Brief 15-19. If such were the approach of this Court, an unduly low threshold for utility ("not . . . detrimental to the public interest") might have been allowed to stand because an inventor still would need to show conception, novelty, and nonobviousness in order to secure a patent. *See Brenner v. Manson*, 383 U.S. 519 (1966). An unduly low novelty threshold might have endured for similar reasons. *See Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147 (1950). In each case, however, this Court examined the relevant criterion and decided that the court of appeals had set the threshold too low.

The Court is cautioned by the Solicitor General that by examining the issue of conception, it might assume a legislative role. U.S. Brief 16. Congress has enacted many patent statutes in the past two centuries but has defined "conception" in none. Indeed, the relevant provisions of the patent code do not even mention conception, 35 U.S.C. §§ 101, 116, and the Federal Circuit noted that Section 116 "does not set forth the minimum quality or quantity of contribution required for joint inventorship." Barr Pet. App. 8a. Moreover, if this Court would be legislating by considering this issue, then the Federal Circuit—over which this Court exercises supervisory authority, *see* S. Ct. R. 10(a)—long has been doing as much.

The Solicitor General questions whether a "reasonable expectation" test for conception in the area of biological science would encourage joint inventorship. *See* U.S. Brief 16. Such a test certainly would do so in this case, and Barr has no reason to doubt that it would do so in other instances as well. Congress has provided deliberately for joint inventorship, adding it to the patent code in 1952, 1 D. CHISUM, PATENTS § 2.02[1] (1995), and expanding it as recently as 1984, Patent Law Amendments Act of 1984, Pub. L. No. 98-622, § 104(a), 98 Stat. 3383, 3384 (codified at 35 U.S.C. § 116).[4] Further, that lawyers might draft around clarifications enunciated by the courts, *see* U.S. Brief 16, hardly is a reason for the latter to forswear clarification. The argument that a reversal might fail to increase competition, U.S. Brief 16-17, suffers from the same shortcomings as that about joint inventorship.

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[4] The 1984 law amended the patent code "to allow inventors to apply for a patent jointly even though (i) they did not physically work together or at the same time, (ii) each did not make the same type or amount of contribution, or (iii) each did not make a contribution to the subject matter of every claim of the patent." 130 Cong. Rec. H10527 (daily ed. Oct. 1, 1984) (analysis of bill).

The Solicitor General's final objection is that "[t]here is no reason to believe . . . that inventors routinely develop documentary evidence of their expectations concerning their inventions' effectiveness." *Id.* 19. In fact, researchers routinely indicate as such and indeed may be required to do so. *E.g.*, 21 C.F.R. § 58.120(a) (FDA rule requiring study protocols to indicate their objectives); *id.* § 58.185(a)(2) (same re reports of study results).

CONCLUSION

For the reasons set forth in the petition, Barr's reply memorandum, and above, the petition for certiorari should be granted.

Respectfully submitted,

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